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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,880	11/30/2000	Chyi-Cheng Chen	20223 US (C38435/120240)	1470
83522	7590	02/05/2010	EXAMINER	
Bryan Cave LLP 1290 Avenue of the Americas New York, NY 10104			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1611	
			MAIL DATE	DELIVERY MODE
			02/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/726,880	Applicant(s) CHEN ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15,17 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of declarations, amendment and response dated 12-7-09 is acknowledged.

New claims 28-35 are submitted. Claims 2, 16 and 18-27 have been canceled. Claims 1 and 3-15, 17 and 28-35 were pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-7-09 has been entered.

2. The following rejection is new and replaces the rejection of record:

3. Claims 1, 3-15, 17 and 28-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Instant claims require a matrix consisting of an emulsion forming composition that is indefinite. It is unclear what the meets and bounds of the said matrix are particularly when the word "matrix" is followed by the term "consists of". A clarification is requested.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 3-14, 17 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US 5,968,251 to Auweter (submitted on PTO 1449 of 12-29-08) in view of US 3998753 to Antoshkiw et al or Auweter and EP 937412 ('412) in view of US 3998753 to Antoshkiw et al.

Auweter teaches cold water dispersible powders comprising fat soluble vitamins such as carotenoids prepared by the method described in abstract and col. 2, L 27-46. For the protective colloids, Auweter teaches the claimed proteins such as fish gelatin, vegetable proteins, and also gum such as gum arabic (col. 4, L 40-53). Auweter teaches a 0.5-20% carotenoids and 10-50% by weight of a protective colloid (col. 4, L 53-59). Auweter teaches particles of 200 nm size (col. 3, L 51-56). For the claimed vitamins of claims 10-11, Auweter teaches carotenoids esters and not the claimed vitamins. Auweter teaches the carotenoids powders for food compositions but not tablet preparations. However, preparing an appropriate form of the composition such as powder or solid tablet or liquid depending on the food preparation would have been within the scope of a skilled artisan. Alternatively, Auweter does not exemplify any compositions with the claimed gums or proteins.

EP '412 teaches finely divided pulverous carotenoids preparations formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, rapidly mixing with a swellable colloid. EP teaches the particle size such as

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213 nm, 225 nm or 400 nm. Among the colloids, EP teaches gelatin, starch, gums, pectin etc (col. 3, L 1-7).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter by incorporating colloids such as polysaccharide gums or proteins such as those taught by Auweter or EP because both references are directed to preparing the claimed powders and further EP suggests colloids such as gelatin and gums as effective in preparing vitamin powder preparations. Further, Auweter suggests preparing the powders with or without an emulsifier and thus meet the claimed matrix claim limitations. Further, EP suggests including carotenoids as well as tocopherol (019) and also suggests particles of less than 400 nm (0009).

Antoshkiw et al (cited in the introduction section of EP reference) US Patent 3,998,753 describes a batch process for the preparation of a water dispersible carotenoid containing powder, wherein the carotenoid has a particle size of less than 1 micron, which process comprises (a) forming a solution of a carotenoid and an antioxidant in a volatile solvent, said solvent being selected from the group consisting of halogenated aliphatic hydrocarbons such as chloroform, carbon tetrachloride and methylene chloride; (b) forming an aqueous solution of sodium lauryl sulfate, a water soluble carrier composition such as e.g. gelatin, a preservative and a stabilizer, and adjusting said solution to a pH of about 10 to 11 and (c) forming an emulsion of the solutions of steps (a) and (b) by mixing at a high speed and high shear; removing the organic solvent and spray drying the resulting emulsion to obtain a carotenoid powder. In col. 2, L 16-24, the above reference teaches high optical clarity of the water

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dispersible powders of carotenoids and further teaches that high speed emulsification employed in the process involves high shear that is essential for obtaining a small particle size (col. 3, L 33-62). The reference also states that the effective shear force is a function of viscosity, solid content, speed of mixing, geometry of mixer and mixing vessel. Furthermore, the reference teaches in order to keep the particle size below 0.1 microns (<100 nm), one has to employ high shear force and high speed mixing.

Thus, a skilled artisan would have been able to prepare the desired particle sizes of carotenoids of Auweter and EP, in particular below 0.1 microns, by optimizing the mixing speed and high shear force such that when dispersed in water the powder results in high optical clarity. Examiner notes that newly added claim 29 recites particle size up to 200 nm, which is taught by Auweter and is within the size range (<400 nm) of EP reference. Thus, applicants have not shown any evidence that one of ordinary skill in the art would not be able to arrive at the claimed particle sizes with the method of Auweter and/or EP.

With respect to the newly added claims 29-35, the claims are directed to a product and not a process. While it is noted that the product claims recite the process limitations, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The examiner notes

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that the product of claim 29 is no different from the product of claim 1 and hence the process steps do not determine the patentability of the claims.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable US 5,968,251 to Auweter (submitted on PTO 1449 of 12-29-08) in view of US 3998753 to Antoshkiw et al **OR** Auweter and EP 937412 ('412) in view of US 3998753 to Antoshkiw et al as applied to claims 1, 3-14, 17 and 28-35 above, and further in view of US 3,886,294 to Emodi et al (Emodi, submitted on PTO 1449 of 12-29-08).

Auweter and EP fail to teach the claimed moisture content.

Emodi also teaches a powder preparation of carotenoids wherein the powder is prepared by mixing fish gelatin with carotenoids crystals and spray drying the resultant solution to a form a stable powder of moisture content less than 2% (example 1 in col. 4). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter or Auweter and EP by spray drying where the final moisture content is less than 2% because Emodi suggests stability of the powders. A skilled artisan would have expected the powders of Auweter to be stable.

Response to Arguments

Applicant's arguments and the Declaration of Mr. Hermann Stein and Dr. Bruno Leuenberger filed 12-7-09 have been fully considered but they are not persuasive.

Firstly, instant claims are now rejected over a new combination of references and hence the arguments and the declarations are not persuasive.

The lengthy response of applicants has not been reproduced here. Applicants argue that Auweter teaches carotenoids that are entirely insoluble in water and discloses "coldwater-dispersible dry powders which contain carotenoids and are obtainable [by the process disclosed] and which have different color effects depending on the production variant" (Col. 1, lines 26-29). It is argued that there is no disclosure in Auweter of any particles size of active substance that does not have at least 200 nm in diameter. While it is true that Auweter teaches 200 nm particles, examiner notes that instant claim 29 also recites 200nm particles. Applicants have not provided any evidence that one of an ordinary skill in the art would not be able to arrive at the claimed sizes (claims 1 and 32) with the methods of Auweter and /or EP.

Applicants argue that the examiner did not provide the reasoning as to why a skilled artisan would arrive at the claimed particle sizes and also why a skilled artisan would modify the teachings of Auweter with that of EP. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843. Applicants merely argue without providing any evidence as to why the less than 400 nm of EP reference does not include claimed sizes and why the process of EP does not result in the claimed sizes. In paragraph 0026, EP states that the carotenoids and the matrix are mixed, emulsified by a homogenizer to a particle size of 150-400 nm. Thus, EP is not strictly limited to 400 nm and a skilled artisan would

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have been to try to optimize the particle size to a desired particle size lower than 400 nm size. On the other hand, the declarations of Stein and Leuenberger does not provide any comparative results showing that the particles sizes of less than 400 nm or the claimed sizes are not possible from the disclosures of EP (or Auweter who teaches 200 nm). EP further suggests in [0017] that swellable colloids suitable for matrix include gelatin, gum arabic, milk proteins, and vegetables proteins, a suggestion that one skilled in the art may be able to employ the colloidal materials of EP in Auweter, i.e., gums, starch, gelatine etc., to prepare the dispersible powders of the instant invention.

Furthermore, the newly cited US patent teaches optical clarity and also the high shear forces to optimize the particle size below 100 nm. Accordingly, even though the response and the declarations of Stein and Leuenberger emphasize in great depth on the two features of the invention, optical clarity of the powders when dispersed in water and particle size, the newly added reference teaches both optical clarity and provides the result-effective variables to achieve the desired particle size. Thus, even though the claims are silent with respect to the optical clarity, the prior art does recognize the arguments and therefore the arguments are not persuasive.

With respect to the new product-by-process claims, the patentability of the process steps in product claims have been explained in the body of the rejection. Additionally, the argument is substantiated by the teachings of the new reference that even though the process steps are different in the prior art Antoshkiw, a skilled artisan would be able to prepare the claimed particle sizes, which in itself is an evidence to the precedent that the patentability of a product does not depend on its method of

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production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Applicants argue that the arguments presented for the teachings of Auweter and EP apply to claim 15 and that Emodi does not overcome the deficiencies of the above references. However, the new rejection addresses the limitations of particle sizes and the unclaimed limitation of optical clarity. Emodi has been cited for moisture content. Thus, the examiner has established a prima facie obviousness for the claimed invention.

Double Patenting

In their response dated 12-7-09, applicants agreed to file a terminal disclaimer upon indicating allowable subject matter. However, at this time no allowable subject matter is indicated. Therefore, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
February 1, 2010